



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1262]

**Notice of Approval of Product under Voucher: Rare Pediatric Disease Priority Review
Voucher**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of vouchers as well as the approval of products redeeming a voucher. FDA has determined that ULTOMIRIS (ravulizumab-cwvz) approved December 21, 2018, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, Fax: 301-796-9858, email: althea.cuff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA

has determined that ULTOMIRIS (ravulizumab-cwvz) approved December 21, 2018, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about ULTOMIRIS (ravulizumab-cwvz) go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: April 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-09005 Filed: 5/2/2019 8:45 am; Publication Date: 5/3/2019]